

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

SURGICAL INSTRUMENT SERVICE
COMPANY, INC.,

Plaintiff/Counter-Defendant,

v.

INTUITIVE SURGICAL, INC.,

Defendant/Counter-Claimant.

Case No. 3:21-cv-03496-VC

Honorable Vince Chhabria

Complaint filed: May 10, 2021

REBUTTAL EXPERT REPORT OF PHILIP J. PHILLIPS

HIGHLY CONFIDENTIAL – ATTORNEYS' EYES ONLY

MARCH 1, 2023

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I. Introduction to Rebuttal Report

1. I have been retained by Haley Giuliano L.L.P. (“HG”) to assist HG on behalf of SIS and provide expert consulting service with respect to the case on various FDA-related issues and questions. My expertise is based on my experience with and knowledge of the Federal Food, Drug and Cosmetic Act (“FDCA”), as well as Food and Drug Administration (“FDA”) regulation and practice.

2. On December 2, 2022, I submitted an opening expert report in this case in which I provided my opinions on the reasonableness of SIS’s efforts to conform with all applicable FDA regulatory requirements in regard to servicing Intuitive Surgical’s EndoWrists. I also provided context for understanding and evaluating SIS’s efforts to conform to applicable regulatory requirements. Finally, I referred to and provided my opinions on whether certain communications Intuitive is alleged to have made to customers, suggesting SIS's servicing of Intuitive Surgical's EndoWrist instruments is contrary to FDA regulations and/or is possibly illegal, are false and misleading.

3. My qualifications, including a description of my current position, a summary of my career, and a copy of my resume which lists my professional publications and presentations, are described in my Opening Report and exhibits to that report.

4. I am submitting this rebuttal report at the request of HG counsel for SIS, the named plaintiff in the lawsuit captioned on the first page of this report. I am being compensated for my work at a rate of \$500 per hour. My compensation is not dependent on the outcome of this case or the opinions I render in this or any other report or declaration I submit in this matter.

5. I have been asked by counsel for SIS to review, analyze, and respond to the expert report submitted on behalf of Intuitive Surgical by Ms. Christy Foreman.¹

6. The purpose of my rebuttal report is not to rehash or retread ground that I have already addressed in my Opening Report, or to respond and rebut every error and flaw I find in the

¹ Expert Report of Christy Foreman, Surgical Instrument Service Company, Inc. v. Intuitive Surgical, Inc., Case No. 3:21-cv-03496-VC, January 18, 2023 (hereafter "Foreman Report").

Foreman Report. The absence of a response to any particular claim or argument does not mean that I agree with it. Further, I have not undertaken the task of identifying and pointing out in this Rebuttal Report each and every misstatement of fact contained in the Foreman Report.

7. A list of materials that I was given access to and from which I sourced the materials I considered in forming my opinions in this Rebuttal Report is attached as **EXHIBIT 1**.

8. In examining the Foreman Report, I note that although new materials are cited, I consider them to be cumulative of materials I have previously considered when preparing my Opening Report in this case.

9. After having reviewed the Foreman Report and materials considered by Ms. Foreman, I reaffirm the opinions that I made in my initial report and disagree with the opinions Ms. Foreman has expressed in her report.

10. Set forth in the following sections are my Rebuttal Opinions with respect to the Foreman Report.

II. Rebuttal Opinion 1 – The term “remanufacturer” is defined in 21 CFR § 820.3(w), however, the definition is not clear and cannot be used to consistently and reliably differentiate remanufacturing from servicing.

11. I offer the above statement as an opinion; however, I believe that this opinion is actually a fact. FDA has publicly acknowledged as recently as June 24, 2021 that “... there is a lack of clarity regarding the distinction between “servicing” and “remanufacturing” of a device”² and has engaged in numerous regulatory activities aimed at gathering information that may offer some degree of clarity.

12. Apart from FDA’s public acknowledgement that the definition is not clear, it is obvious from reading the definition that reasonable people will interpret the wording in different ways depending on the situation in which it is being applied. While I agree with Ms. Foreman that

² U.S. Food and Drug Administration, "Remanufacturing of Medical Devices -- Draft Guidance for Industry and Food and Drug Administration Staff", June 24, 2021, <https://www.fda.gov/media/150141/download>

“Remanufacturing medical devices is a manufacturing activity, which is subject to FDA regulatory requirements, including premarket notification, registration, … among others”, I strongly disagree that the definition of “remanufacturing”, containing the words “significantly changes”, is clear and can be consistently and reliably interpreted and applied at this point in time.

13. Ms. Foreman states that “… there is no doubt that a party that engages in the activities described in the regulation is a remanufacturer.” This statement is inaccurate and completely overlooks the fact that it is not simply “the activities described in the regulation” that cause a party to be considered a remanufacturer, but rather the consequence of the activities described in the regulation.

14. According to 21 CFR §820.3(w), to be a “remanufacture” a party not only “… processes, conditions, renovates, repackages, restores, or does any other act to a finished device” (i.e., the only activities to which Ms. Foreman refers), but must also do so to a degree “that **significantly changes** the finished device's performance or safety specifications, or intended use. [emphasis added].” FDA has not modified the regulation, or issued a guidance document, sufficient to allow anyone to differentiate significant changes from insignificant ones. Indeed, all of FDA's actions have been geared toward developing an understanding of how such a differentiation can be made in the extremely broad context of medical device regulation. To illustrate FDA's dilemma, consider how much money can significantly change a person's life? While we would all likely agree that a billion dollars would change anyone's life, a million dollars would not likely change the life of a billionaire and many multi-millionaires. On the other hand, a small child may consider \$20 to be significant. It may not significantly change the child's life, but time can render amounts much less than a million dollars to have a significant impact over a lifetime.

15. Relevant to the SIS and Intuitive Surgical dispute involving servicing EndoWrist instruments, in its 2018 *White Paper: Evaluating Whether Activities are Servicing or*

*Remanufacturing*³ among the “... hypothetical examples of activities that may be performed on medical devices that **may constitute servicing or remanufacturing ...** [emphasis added]”, FDA described a scenario that is remarkably similar to the situation in this case. By including Hypothetical 5 - Non-device Specific Examples/Example B, FDA certainly telegraphed uncertainty with whether a 3rd party’s activities performed to extend an original equipment manufacturer (“OEM”) device’s intended use life constitute remanufacturing or servicing; a question that certainly has not yet been answered in any subsequent FDA guidance documents issued to date.

16. FDA appears to be on a path to clarify the meaning of the words “significantly changes” through the development and issuance of a guidance document. Based on my experience this process will likely take years to complete and, in the end, will not eliminate disagreements or provide a consistent and reliable means to differentiate remanufacturing and servicing to a degree that will support many enforcement actions.

III. Rebuttal Opinion 2 - Like all devices, the EndoWrist will fail with use and the passage of time, but FDA has not established a use limitation that will avoid such failure.

17. In considering a device’s safety and effectiveness, FDA considers (1) the conditions of use for the device and (2) the reliability of the device, among other factors.⁴ In so doing, I am unaware of FDA ever establishing a limitation on the number of uses for any device, other than one that cannot be cleaned, sterilized or disinfected, and checked for functionality between uses involving different patients. To do so, FDA would have to mandate testing “to failure” under simulated use conditions as a class II special control or, in the case of a class III device, through premarket approval.

18. FDA found the EndoWrist substantially equivalent to a legally marketed class II endoscope regulated under *21 CFR 876.1500 Endoscope and accessories*. In doing so, the Agency

³ The report, published in May, 2018, is available at <https://www.fda.gov/downloads/RegulatoryInformation/LawsEnforcedbyFDA/SignificantAmendments/totheFDCAct/FDARA/UCM607469.pdf>.

⁴ 21 CFR § 860.7(b)(2) and (4)

did not see fit to promulgate class II special controls for the EndoWrist or any other devices regulated under this *generic type of device*.⁵ Without a special control, the EndoWrist is actually regulated very much like a class I device, subject to only the general controls of the FDCA. Indeed, many legally marketed endoscopes have no OEM mandated usage limit.

19. It was Intuitive that designed the EndoWrist and performed life and performance testing which was submitted to FDA in its 510(k) submissions to support its usage limitation in its device labeling. Whether Intuitive did so on its own initiative or to meet FDA ‘expectations,’ is irrelevant. FDA has not taken the steps that would be necessary to restrict the use of the EndoWrist, except as a prescription device for use by or on the order of a licensed healthcare provider.

IV. Rebuttal Opinion 3 – It is inappropriate to conflate regulatory requirements that apply to OEMs and third party reprocessors of SUDs with FDA regulation of remanufacturers or servicers.

20. Ms. Foreman conflates aspects of FDA regulation of medical devices that are irrelevant to this case and inappropriately attempts to make them analogous and/or relevant. While it may seem reasonable to consider the regulatory requirements that apply to OEMs that modify their, previously cleared or approved, legally marketed devices and apply them in the context of what may constitute remanufacturing or servicing of those devices, there are significant differences in the regulations that preclude applying a regulation or FDA guidance for one to the other. The same can be said about reprocessors of single-use disposable devices (“SUDs”).

21. In the context of OEMs changing or modifying their legally marketed class I or class II devices, 21 CFR § 807.81(a)(3) uses the words “significantly changed” and further defines significant changes as those that “could significantly affect the safety or effectiveness [emphasis added]” of the device or constitute a “major change” in the device’s intended use. Putting the

⁵ 21 CFR § 860.3(i)

challenges of determining the “significance” of a change aside, based on the construct of this regulation, OEMs have the responsibility to file 510(k)s for virtually any change to a device simply because of the potential for the change to significantly affect safety and effectiveness. To avoid receiving 510(k)s for virtually all changes, including those that are unlikely to significantly affect safety or effectiveness, FDA developed and issued two guidance documents to industry and FDA staff to reflect its thinking on what changes “**could** significantly affect safety and effectiveness [emphasis added]” or constitute a “major change” in intended use. These guidance documents, however, have no bearing on interpreting similar wording appearing in *21 CFR § 820.3(w)*.

22. In regard to remanufacturing, the Quality System regulation, specifically, *21 CFR § 820.3(w)*, defines “*Remanufacturer*” as “any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device **that significantly changes** the finished device's performance or safety specifications, or intended use. [emphasis added]” Unlike *21 CFR § 807.81(a)(3)*, *21 CFR § 820.3(w)* does not even attempt to clarify or define the words “significantly changes.” By regulation, OEMs may need to file 510(k)s because of the mere potential for a change to significantly affect safety and effectiveness, whereas to be considered a “remanufacturer,” the activity must have more than the mere potential to significantly change the device (i.e., could do so), it must actually and in fact significantly change the device.

23. To illustrate the inappropriateness of conflating regulations that apply to OEM activities with activities that constitute remanufacturing, consider the fact that a specific change to a device made by an OEM could require a 510(k) simply because of its potential to significantly affect the device’s safety and effectiveness. Of course, FDA clearance of the OEM’s 510(k) would establish that the changed device is as safe and effective as the device before the change was made; thereby putting the change’s actual, real-world significance in question. While I am unwilling to conflate these regulations as part of my rebuttal, I will point out that a change that an OEM makes to its device

may require a 510(k) clearance and yet fall short of being a change that would cause a third party making the very same change to be considered a remanufacturer.

24. FDA took over 10 years to develop guidance for interpreting and applying 21 CFR 807.81(a)(3) to OEMs. Even after issuing guidance to industry and FDA staff, FDA limited the internal organizations that were empowered to apply the guidance and take enforcement actions against regulated companies for violating the regulation.⁶ Because of ever evolving medical technology, FDA has since updated its guidance and issued a separate guidance devoted to OEM changes in software. Even with FDA's guidance documents now in place, disagreement regarding the interface of device changes and 510(k) requirements continue with regularity.

25. In regard to any comparisons to reprocessors of SUDs, it is critically important to understand that the EndoWrist is not a single-use disposable device, therefore, on its face it is unreasonable and improper to in any way apply the law, regulations and FDA guidance documents that were developed in regard to the Agency's regulation of SUDs to other situations. A Compliance Policy Guide (CPG)⁷ sums up the FDCA, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) that addressed reprocessing SUDs, as well as FDA's current thinking on the regulation of those particular types of medical devices. The scope of the CPG expressly does not encompass multiple-use devices and is limited as follows:

This guidance addresses the practice of reprocessing devices that are labeled or intended for single use.

26. While FDA's rules for reprocessing SUDs have no direct implications for devices like the EndoWrist, the history of FDA regulation of reprocessing SUDs is informative. The reprocessing of SUDs dates back to before the enactment of the Medical Device Amendments of 1976 (MDA) to

⁶ FDA. Johnson R, Director of the Office of Compliance. Memorandum to Office of Compliance Staff. 29 Jun. 1994

⁷ FDA. CPG Sec. 300.500. Reprocessing of Single Use Devices. 18 Mar. 2005

the FDCA. For the 25 years following enactment of the MDA, FDA exercised “enforcement discretion” and did not regulate reprocessing of SUDs. Although I do not know the date on which FDA began reconsidering its long-standing position regarding the reprocessing of SUDs, I know that it was well before the conference on Reuse of Single-Use Devices held in May, 1999 that FDA cosponsored with the Association for the Advancement of Medical Instrumentation (AAMI).⁸ It was not until August 14, 2000 that the Agency announced a prioritization schedule for enforcing the premarket submission requirements for SUD reprocessors which required 510(k) submissions for class II devices within 12 months and class I devices within 18 months. The FDA did not release its revised Compliance Policy Guide on the Reprocessing of Single Use Devices until nearly five years (March 18, 2005) after the enforcement prioritization schedule was announced.⁹ The transition from enforcement discretion to active regulation took years and did not involve the arduous task of defining what constitutes “significant changes” or require differentiating SUD reprocessing from other commercial activities. When one considers the time and steps required for FDA to change its regulatory position on reprocessing SUDs, in light of the substantial challenges to clearly defining or interpreting vague terminology in a federal regulation, one can see that it could easily take years for FDA to be in a position to clearly differentiate remanufacturing from servicing.

27. In regard to FDA review staff referencing and applying existing guidance documents that relate to reprocessing SUDs to activities involving multiple-use devices, from scientific and efficiency perspectives, doing so may make sense, however, in a broader context, doing so is completely inappropriate. Before any scientific guidance relating to remanufacturing or servicing can issue, FDA must first define the words “significantly changes” in the context of 21 CFR § 820(w) and define the word “service.”

⁸ 64 Fed. Reg. 212 (Nov. 3, 1999) at 59782- 59783.

⁹ FDA. CPG Sec. 300.500. Reprocessing of Single Use Devices. 18 March 2005.

V. Rebuttal Opinion 4 – A clear understanding of FDA regulation and standard operating procedures is needed in order to avoid drawing erroneous inferences from FDA actions.

28. In the premarket review organization hierarchy, reviewers are among the lowest level of professionals and have no delegated decision-making authority.¹⁰ Nevertheless, for the efficient operation of the review process, reviewers often communicate directly with regulated industry with little supervision. While these communications are controlled and documented, it is not unusual for FDA reviewers to request information that may be unreasonable or unnecessary. Unfortunately, the system does not identify all unnecessary or unreasonable requests. Some companies simple provide the information, thereby perpetuating the problem, while others negotiate an alternative or speak with a supervisor. The point is that requests for information, even when met by the recipient, do not always reflect official, sanctioned and authorized FDA policy, practice or good regulatory science.

29. Incoming premarket submissions are logged in by the Agency and directed to the attention of the first line supervisor, believed to be responsible for review of the device type, for assignment to a team leader or reviewer. Submissions are first screened for administrative completeness, basically to ensure that the submission content requirements are met. If administratively complete, submissions are substantively reviewed and requests for additional information are frequent and can be lengthy and detailed. For all but few submissions, there is no assessment of whether the particular submission is required. Unless it is obvious that the device is class III (subject to premarket approval), there is a question as to whether the subject of the submission is a device, or the 510(k) raises an unusual issue (e.g., contains a drug or biologic), the submission merely moves along to the step of substantive review for substantial equivalence.

30. For devices that represent OEM changes to their own legally marketed class I or class

¹⁰ FDA. SMG 1410.406 - Delegations of Authority. Determination Of Classification of Devices. 13 Nov. 2018

II devices, FDA does not evaluate the change to determine its significance, nor does FDA question whether the submission was necessary. FDA simply performs a substantive review of the submission to determine whether the device is substantially equivalent. Although Ms. Foreman states that in her “... experience, FDA does not devote the necessary resources to identify and describe deficiencies at this level of detail where FDA considers the 510(k) “unnecessary” (referring to FDA correspondence regarding 510(k) submission cited in her report), determining the necessity of all premarket submissions is not an Agency responsibility. Further, such a determination could not be made without conducting a thorough review. The bottom line is that FDA substantively reviews all administratively complete 510(k)s and clears all 510(k)s where the subject device does not significantly differ from the predicate device. For devices that are significantly different, FDA answers basic questions to determine eligibility for 510(k) clearance and relies on data to determine if the device is as safe and effective as the device with which it is being compared.

31. Product codes are used in identifying and tracking devices, or premarket submissions, associated with attributes or characteristics of interest, however, establishing a product code is nothing more than a simple administrative action taken most often at the lowest levels of the Agency. Rarely do higher level employees request that a new product code be established. Typically, the lead reviewer, or first line supervisor, requests issuance of a new product code to be assigned to a device when a final decision on a premarket submission is made and someone recognizes a need to create an ability to search the FDA database for certain submissions or devices with certain attributes. The fact that the “QSM” product code was created for a device cleared as a remanufactured NAY instrument and refers to a “System, Surgical, Computer Controlled Instrument, Remanufactured”, is not evidence of an FDA determination that the activities described in the 510(k) submission constitute remanufacturing as opposed to servicing. As stated in my Opening Report, clearance of such a 510(k) results in a classification decision that subjects the 510(k) submitter to the applicable regulatory

controls of the FDCA. The decision does not establish that the submitter significantly changed the device and is a remanufacturer, nor does it prohibit the submitter from engaging in any servicing activities.

32. In regard to FDA's clearance of Iconocare Health's 510(k) K210478 (assigned product codes "QSM" and "NAY"), the only reasonable inference that can be drawn is that Iconocare Health's device, referred to as "8mm Monopolar Curved Scissors", has the same intended use and technological characteristics as the legally marketed predicate devices with which it was compared (all manufactured by Intuitive Surgical). If there had been a change in intended use, Iconocare Health's 510(k) would not have been substantively reviewed. After the substantive review, FDA's overall finding is clearly stated in its 510(k) Summary for 510(k) K210478 as follows:

The design, materials, and intended use of the 8mm Monopolar Curved Scissors Instruments, after an additional ten (10) reuse cycles are equivalent to the predicate device. The mechanism of action of the reusable device is identical to the predicate device in that the same standard mechanical design, materials, and sizes are utilized. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation. Each individual device is tested for appropriate function of its components prior to packaging and labeling operations.^{11,12}

33. As a result of the clearance of 510(k) number K210478, Iconocare Health can commercial distribute its 8mm Monopolar Curved Scissors to any healthcare facility, as long as it packages and labels its device under its own name and complies "with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or post marketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety->

¹¹ Based on FDA's 510(k) Summary and in accordance with 21 CFR §§ 807.100(b)(1) and (2)(i), FDA had no choice but to find Iconocare Health's device SE as it is the same as the predicates.

¹² Refer to the FDA 510(k) Summary for 510(k) K210478 available at https://www.accessdata.fda.gov/cdrh_docs/pdf21/K210478.pdf.

reporting combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531- 542 of the Act); 21 CFR 1000-1050.”¹³

34. The clearance of 510(k) number K210478 does not establish or even justify inferring that Iconocare significantly changed a legally marketed device and is a remanufacturer, nor does it resolve all of the policy issues that FDA has been struggling with for over 20 years to clarify what constitutes remanufacturing and servicing and how the two can be clearly differentiated.¹⁴

35. As a threshold matter, FDA doesn’t determine whether or not the particular change that prompted the submission actually could affect safety and effectiveness and thus required the filing of a 510(k). FDA reviews each 510(k) submission to determine substantial equivalence to a predicate device. FDA’s initial review process merely examines whether the content requirements have been fulfilled and whether sufficient information is present to assess substantial equivalence. If the submission meets the content requirements and sufficient information, to include any needed performance data, a detailed review begins. If the data demonstrates substantial equivalence, a letter issues that allows the device to be commercially distributed. When content requirements are not met or sufficient information to assess substantial equivalence is not provided, FDA requests additional information and these requests can be lengthy and detailed. In any event, there is no FDA review to ensure that the changes that prompted the 510(k) filing are in fact actually significant or could be significant. To be clear, if a manufacturer makes a completely innocuous change to its legally marketed class II device that does not require FDA premarket authorization, but elects to file a 510(k) claiming substantial equivalence to its legally marketed predicate device, the 510(k) will be reviewed

¹³ Refer to the FDA order associated with 510(k) K210478 available at https://www.accessdata.fda.gov/cdrh_docs/pdf21/K210478.pdf.

¹⁴ 81 Fed. Reg. 43 (Mar. 4, 2016).

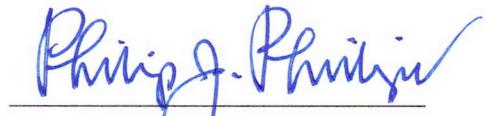
and it will be cleared by FDA. If that 510(k) does not fulfill the content requirements in 21 CFR 807.87, and/or fails to include sufficient information for FDA to complete a substantive review, the missing information will be requested and the submission put on hold until the information is received. The entire focus of FDA's review is on substantial equivalence and not evaluating or determining whether the 510(k) is necessary for any given change to a device. Of course, unnecessary 510(k)s are filed and some will be the subjects of extensive requests for information.

VI. Conclusion

36. Nothing in Ms. Foreman's expert report causes me to change the opinions I expressed in my opening report. In order to understand the regulatory issues that are relevant to this particular case, and to properly interpret the facts, not only is experience in FDA medical device regulation required, but also an appreciation of what is required to define the scope of the Agency's authority and determine whether and how specific situations fall within that scope. It remains my position that at the time SIS was setting up its "servicing" operation in regard to Intuitive Surgical's EndoWrists, the company was not subject to active FDA regulation (specifically, registration and listing, premarket notification/510(k) requirements, and the QSR). Based on the information that I have reviewed in the context of this case and presented in my opening report and this report, it is my opinion that SIS is not a remanufacturer, as that term is defined by FDA, and that the company acted reasonably in its effort to conform with all applicable FDA medical device requirements. Any suggestion that SIS's planned commercial activities, with respect to Intuitive Surgical's EndoWrist instruments, are contrary to the FDCA and will cause customers to violate the law, is false and misleading.

If called upon to testify at trial, I expect to prepare additional demonstrative materials reflecting the opinions set forth in this Rebuttal Report.

Executed on March 1, 2023

A handwritten signature in blue ink that reads "Philip J. Phillips". The signature is fluid and cursive, with "Philip J." on top and "Phillips" on the bottom, all connected by a single continuous line.

Philip J. Phillips

Exhibit 1

Bates-Stamped Documents

- ACG000006
- AHP000369
- AHP000373
- AHP000404
- AHP000525
- AHP000527
- AHP000658
- AHP000706
- AHP000708
- AHP000729
- AHP000732
- AHP000803
- AHP000832
- AHP000928
- AHP000939
- AHP002062
- AHP002130
- AHP002395
- AHP002448
- AHP002623
- AHP002680
- AHP003709
- AHP005099
- BPI000331

- Intuitive-00000501
- Intuitive-00000518
- Intuitive-00091257
- Intuitive-00091260
- Intuitive-00091261
- Intuitive-00202493
- Intuitive-00481165
- Intuitive-00481167
- Intuitive-00481176
- Intuitive-00491017
- Intuitive-00492705
- Intuitive-00493504
- Intuitive-00493612
- Intuitive-00499468
- Intuitive-00515501
- Intuitive-00512045-00512407
- Intuitive-00552632
- Intuitive-00552635
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- Intuitive-00691203
- Intuitive-00691613
- Intuitive-00691658
- Intuitive-00691660
- Intuitive-00691710
- Intuitive-00691802
- Intuitive-00691837
- Intuitive-00691847
- Intuitive-00691857
- Intuitive-00692185
- Intuitive-00692310
- Intuitive-00692314
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- Intuitive-02068246
- Intuitive-02070398
- Intuitive-00208694
- Intuitive-00212457
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- REBOTIX077617
- REBOTIX077671
- REBOTIX077735
- REBOTIX077440
- REBOTIX077729
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- REBOTIX124467-REBOTIX124705
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- REBOTIX131501
- REBOTIX131514

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- Restore-00010132
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- Consolidated Amended Class Action Complaint, In re: da Vinci Surgical Robot Antitrust Litigation, Lead Case No. 3:21-cv-03825-VC (ECF 52) (Sept. 9, 2021)
- Defendant Intuitive Surgical, Inc.’s Answer, Affirmative Defense and Counterclaims, Surgical Instrument Service Co., Inc. v. Intuitive Surgical, Inc., No. 3:21-cv-03496-VC (ECF 75) (Dec. 14, 2021)
- ECF Dkt. 51, SIS’s Opposition to Defendant’s Motion to Dismiss, August 20, 2021
- SIS Response to Intuitive Interrogatory No. 5
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Depositions

Deposition Transcripts and Exhibits (*SIS* and *Larkin*)

- Depositions of Clifton Parker (Oct. 25, 2022) and Exhibits
- Deposition of Disha Peswani (Oct. 6, 2022) and Exhibits
- Deposition of Grant Duque (30(b)(1)) (Nov. 8, 2022) and Exhibits
- Deposition of Grant Duque (30(b)(6)) (Nov. 8, 2022) and Exhibits
- Deposition of Greg Posdal (30(b)(1)) (Nov. 1, 2022) and Exhibits
- Deposition of Greg Posdal (30(b)(6)) (Nov. 1, 2022) and Exhibits
- Deposition of Greta Bernier (Nov. 7, 2022) and Exhibits
- Deposition of John Sampson (Nov. 3, 2022) and Exhibits
- Deposition of Jose Gonzalez (30(b)(1)) (Oct. 17, 2022) and Exhibits
- Deposition of Jose Gonzalez (30(b)(6)) (Oct. 17, 2022) and Exhibits
- Deposition of Keith Johnson (30(b)(1)) (Oct. 27, 2022) and Exhibits
- Deposition of Keith Johnson (30(b)(6)) (Oct. 27, 2022) and Exhibits
- Deposition of Kevin May (Nov. 3, 2022) and Exhibits

- Deposition of Nicky Goodson (Oct. 27, 2022) and Exhibits
- Deposition of Ricardo Estape, M.D. (Oct. 22, 2022) and Exhibits
- Deposition of Rick Ferreira (Nov. 10, 2022) and Exhibits
- Deposition of Sharathchandra “Shark” Somayaji (Nov. 4, 2022) and Exhibits
- Deposition of Stan Hamilton (Nov. 4, 2022) and Exhibits

Deposition Transcripts and Exhibits (*Restore*)

- Deposition of Clifton Parker (30(b)(6)) (May 4, 2021) and Exhibits
- Deposition of Eugene Dickens, M.D. (May 27, 2021) and Exhibits
- Deposition of Kevin May (May 6, 2021) and Exhibits
- Deposition of Kevin May (June 8, 2021) and Exhibits
- Deposition of Rafal Chudzik (June 7, 2021) and Exhibits
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Deposition Transcripts and Exhibits (*Rebotix*)

- Deposition of David Mixner (June 10, 2021) and Exhibits
- Deposition of Edward Harrich (May 24, 2021) and Exhibits
- Deposition of Stan Hamilton (Sept. 20, 2021) and Exhibits

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- Expert Report of Philip Phillips (Dec. 2, 2022) (*Surgical Instrument Service Company Inc. v. Intuitive Surgical, Inc.*)
- Expert Report of Dr. Robert D. Howe (Aug. 20, 2021) (*Restore Robotics LLC et al. v. Intuitive Surgical, Inc.*)
- Supplemental Expert Report of Dr. Robert D. Howe (Dec. 23, 2022) (*Restore Robotics LLC et al. v. Intuitive Surgical, Inc.*)
- Expert Report of Dr. Robert D. Howe (Dec. 2, 2022) (*Surgical Instrument Service Company, Inc. v. Intuitive Surgical, Inc.*)
- Expert Report of Kurt Humphrey (Dec. 2, 2022) (*Surgical Instrument Service Company, Inc. v. Intuitive Surgical, Inc.*)
- Expert Report written by Heather S. Rosecrans, *Rebotix Repair LLC v. Intuitive Surgical*

Inc., Case No. 8:20-cv-02274, July 26, 2021

- Expert Rebuttal Report written by Heather S. Rosecrans, *Rebotix Repair LLC v. Intuitive Surgical, Inc.*, Case No. 8:20-cv-02274, August 30, 2021
- Expert Report written by J. Lawrence Stevens, *Rebotix Repair LLC v. Intuitive Surgical, Inc.*, Case No. 8:20-cv-02274, August 30, 2021
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